D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 2 of 18

Listing of Claims:

- 1. (Currently Amended) An apparatus for placing a proximal portion of a penetrating memberneedle in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area by a manipulation device, the penetrating memberneedle having a translational axis, said apparatus comprising:
- a first arm being configured and arranged to rotatably support the penetrating memberneedle about its translational axis;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the <u>needle penetrating member</u> along its translational axis in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the <u>penetrating memberneedle</u> proximal portion is disposed in the target area;

wherein the first arm and first drive mechanism are coupled to the manipulation device such that the manipulation device can position the apparatus in proximity to the entry point of the object containing the target area; and

- a second drive mechanism being coupled to the <u>needle penetrating member</u> and being configured and arranged so as to cause the <u>penetrating memberneedle</u> to rotate about translational axis of the <u>penetrating memberneedle</u>.
- 2. (Currently Amended) The apparatus of claim 16, wherein the first arm is further configured and arranged to rotatably support the penetrating memberneedle about the translational axis of the penetrating memberneedle; and wherein the apparatus further comprises:
- a second drive mechanism being coupled to the <u>penetrating memberneedle</u> and being configured and arranged so as to cause the <u>penetrating memberneedle</u> to rotate about the translational axis of the <u>penetrating memberneedle</u>.
- 3. (Currently Amended) The apparatus of claim 2 wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the penetrating memberneedle are separately and independently controlled.

D. Stoianovici, et al. U.S.S.N.: 09/943,751

Page 3 of 18

- 4. (Currently Amended) The apparatus of claim 2, wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the penetrating memberneedle are performed at the same time.
- 5. (Currently Amended) The apparatus of claim 2, wherein the first and second drive mechanisms are configured and arranged so as to do one of translating of the first arm or rotating of the penetrating memberneedle.
- 6. (Currently Amended) The apparatus of claim 2, wherein the second drive mechanisms is configured and arranged so as to selectively rotate the penetrating memberneedle at one of a number of different rotational speeds.
- 7. (Previously Presented) The apparatus of claim 16, further comprising a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm.
- 8. (Currently Amended) The apparatus of claim 7, in which the second arm further includes a guide mechanism in which the penetrating memberneedle is moveably received.
- 9. (Currently Amended) The apparatus of claim 8, wherein the guide mechanism is selectively configurable so as to be capable of guiding differently sized penetrating memberneedles.
- 10. (Previously Presented) The apparatus of claim 16, wherein the first arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the first arm.
- 11. (Original) The apparatus of claim 7, wherein the second arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the second arm.

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 4 of 18

- 12. (Currently Amended) The apparatus of claim 11 wherein the detachable portion includes at least a portion of a guide mechanism in which the penetrating memberneedle is moveably received.
- 13. (Previously Presented) The apparatus of claim 16, wherein the first drive mechanisms includes a slipless transmission assembly.
- 14. (Previously Presented) The apparatus of claim 16, wherein the first drive mechanism comprises a screw mechanically coupled to the first arm such that rotation of the screw causes the first arm to translate from the first position.
- 15. (Original) The apparatus of claim 14, wherein the first drive mechanism further includes a bi-directional motor coupled to the screw and wherein the first arm can be translated in one of two direction responsive to the direction of rotation of the motor.
- 16. (Currently Amended) An apparatus for placing a proximal portion of a needleponetrating member in a target area, the needle penetrating member-having a translational axis, comprising:
- a first arm being configured and arranged to rotatably support the <u>needle penetrating</u> member-about the translational axis of the <u>needle penetrating member</u>;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, wherein one of the any of a number of other positions corresponds to a condition where the <u>needle penetrating member-proximal portion</u> is disposed in the target area; and

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates.

17. (Original) The apparatus of claim 16, wherein the linear guide comprises:

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 5 of 18

a rod member;

a track;

a sliding member a portion of which is configured to slidably engaged the track and which is secured to the first arm; and

a coupling mechanism secured to the sliding member and slidably coupling the rod member to the sliding member.

- 18. (Original) The apparatus of claim 2, further comprising:
- a controller that is configured and arranged to selectively and separately control the first and second drive mechanisms.
- 19. (Currently Amended) The apparatus of claim 18, wherein the controller is further configured so as to include a plurality of pre-established penetrating memberneedle driving protocols for driving the penetrating memberneedle end portion from an initial position to the target area.
- 20. (Currently Amended) The apparatus of claim 18, wherein the controller is configured and arranged so that translating of the first arm and rotating of the penetrating memberneedle are performed at the same time.
- 21. (Currently Amended) The apparatus of claim 18, wherein the controller is configured and arranged so as to do one of translating of the first arm or rotating of the penetrating memberheedle.
- 22. (Currently Amended) The apparatus of claim 18, wherein the controller is configured and arranged so as to selectively rotate the penetrating memberneedle at one of a number of different rotational speeds.

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 6 of 18

- 23. (Currently Amended) The apparatus of claim 18, wherein the controller is configured and arranged so as to successively translate the penetrating member needle in a back and forth manner.
- 24. (Currently Amended) The apparatus of claim 18 further comprising a sensor and wherein the controller is configured and arranged to alter the penetrating memberneedle driving protocol based on signals from the sensor.
- 25. (Currently Amended) The apparatus of claim 16, wherein the penetrating memberneedle is configured so as to be capable of performing any one of injecting therapeutic agents into the target area, locating an imaging device in the target area, biopsy including tissue biopsy, and locating a medical device in the target area to be used to perform an medical procedure.
- 26. (Currently Amended) An apparatus for placing a proximal portion of a <u>needle</u> penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the <u>needlepenetrating member</u>-having a translational axis, said apparatus comprising:
- a first arm being configured and arranged to rotatably support the <u>needle penetrating</u> member about the translational axis of the penetrating member;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the <u>needle penetrating member</u> along its translational axis in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the <u>needle penetrating member</u>-proximal portion is disposed in the target area;
- a second drive mechanism being coupled to the <u>needle penetrating-member</u> and being configured and arranged so as to cause the <u>needle penetrating member</u> to rotate about the translational axis of the penetrating memberneedle; and

D. Stoianovici, et al. U.S.S.N.: 09/943,751

Page 7 of 18

wherein the second drive mechanism comprises a gear member secured to the needle penetrating member and being mechanically coupled to a motor such that operation of the motor causes the needle penetrating member-to rotate about its translational axis.

27. (Canceled)

- 28. (Currently amended) The apparatus of claim 56 27, wherein the motor is a bidirectional motor and wherein the penetrating member can be rotated in one of a clockwise and counter clockwise direction responsive to the direction of rotation of the motor.
- 29. (Currently Amended) An apparatus for placing a proximal portion of a penetrating memberneedle in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the penetrating memberneedle having a translational axis, said apparatus comprising:
- a first arm being configured and arranged to rotably support the penetrating memberneedle about the translational axis of the penetrating memberneedle;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating memberncedle proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating memberneedle proximal portion is disposed in the target area;

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates;

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm; and

a second drive mechanism being coupled to the penetrating memberneedle and being configured and arranged so as to cause the penetrating memberneedle to rotate about the translational axis of the penetrating memberneedle.

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 8 of 18

- 30. (Currently Amended) The apparatus of claim 29 wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the penetrating memberneedle are separately and independently controlled.
- 31. (Currently Amended) The apparatus of claim 29, wherein the first and second drive mechanisms are configured and arranged so that translating of the first arm and rotating of the penetrating memberneedle are performed at the same time.
- 32. (Currently Amended) The apparatus of claim 29, wherein the first and second drive mechanisms are configured and arranged so as to do one of translating of the first arm or rotating of the penetrating memberneedle.
- 33. (Currently Amended) The apparatus of claim 29, wherein the second drive mechanisms is configured and arranged so as to selectively rotate the penetrating memberneedle at one of a number of different rotational speeds.
- 34. (Currently Amended) The apparatus of claim 29, in which the second arm further includes a guide mechanism in which the penetrating memberneedle is moveably received.
 - 35. (Original) The apparatus of claim 29, wherein:

the first arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the first arm; and

the second arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the second arm.

- 36. (Original) The apparatus of claim 29, wherein the first drive mechanism comprises:
- a screw mechanically coupled to the first arm such that rotation of the screw causes the first arm to translate from the first position;
 - a bi-directional motor coupled to the screw; and

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 9 of 18

wherein the first arm is translated in one of two direction responsive to the direction of rotation of the motor.

- 37. (Canceled)
- 38. (Previously Presented) The apparatus of claim 29, wherein the linear guide comprises:
 - a rod member;
 - a track;
- a sliding member a portion of which is configured to slidably engaged the track and which is secured to the first arm; and
- a coupling mechanism secured to the sliding member and slidably coupling the rod member to the sliding member.
- 39. (Original) The apparatus of claim 29, further comprising a controller that is configured and arranged to selectively and separately control the first and second drive mechanisms.
 - 40. (Canceled)
- 41. (Currently Amended) The apparatus of claim <u>57.40</u>, wherein the motor is a bidirectional motor and wherein the penetrating member can be rotated in one of a clockwise and counter clockwise direction responsive to the direction of rotation of the motor.
- 42. (Currently Amended) An apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body, the penetrating memberneedle having a translational axis, said apparatus comprising:
- a first arm being configured and arranged to rotatably support the needle about the translational axis of the needle;

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 10 of 18

a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating memberneedle proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm;

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates;

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle; and

wherein the second arm further includes a guide mechanism in which the needle is moveably received.

43. (Original) The apparatus of claim 42, wherein:

the first arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the first arm; and

the second arm includes a detachable portion and a latching mechanism configured so as to releasably secure the detachable portion to a rest of the second arm.

- 44. (Previously presented) An apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body, said apparatus comprising:
- a first arm being configured and arranged to rotatably support the needle about the translational axis of the needle;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

•

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 11 of 18

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm,

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle;

wherein the second arm further includes a guide mechanism in which the needle is moveably received; and

wherein the first drive mechanism comprises:

a screw mechanically coupled to the first arm such that rotation of the screw causes the first arm to translate from the first position;

a bi-directional motor coupled to the screw;

wherein the first arm is translated in one of two direction responsive to the direction of rotation of the motor; and

a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates, wherein the linear guide includes:

a rod member.

a track.

a sliding member a portion of which is configured to slidably engaged the track and which is secured to the first arm, and

a coupling mechanism secured to the sliding member and slidably coupling the rod member to the sliding member.

- 45. (Previously presented) An apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body, said apparatus comprising:
- a first arm being configured and arranged to rotatably support the needle about the translational axis of the needle;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, , thereby also translating the penetrating member proximal portion in a

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 12 of 18

direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area;

a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm;

a second drive mechanism being coupled to the needle and being configured and arranged so as to cause the needle to rotate about the translational axis of the needle;

wherein the second arm further includes a guide mechanism in which the needle is moveably received; and

wherein the second drive mechanism comprises:

a gear member secured to the penetrating member;

a drive gear that is mechanically coupled to the motor and the penetrating member gear member so that the penetrating member gear member rotates responsive to rotation of the motor;

wherein the motor is a bi-directional motor; and

wherein the penetrating member can be rotated in one of a clockwise and counter clockwise direction responsive to the direction of rotation of the motor.

46. (Currently Amended) A method for localizing a proximal portion of a penetrating memberneedle in a target area of a body, the penetrating memberneedle having a translational axis, comprising the steps of:

supporting the ponetrating memberneedle from a first arm;

positioning the first arm with respect to the body so the translational axis of the penetrating memberneedle passes through the target area;

linearly translating the first arm from an initial position to any of a number of other positions spaced from the initial, thereby also translating the penetrating memberneedle proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating memberneedle proximal portion is disposed in the target area; and

rotating the penetrating memberneedle about the translational axis of the penetrating memberneedle.

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 13 of 18

47. (Canceled)

- 48. (Currently Amended) The method of claim 46, wherein said steps of rotating said penetrating memberneedle and translating the first arm are concurrently performed as the penetrating memberneedle proximal portion is translated through a surface of the body.
- 49. (Currently Amended) The apparatus of claim 1, wherein the first arm is operably coupled to the manipulation device that positions the first arm with respect to the entry point of the object containing the target area so a long axis of the penetrating memberneedle passes through the target area.
- 50. (Currently Amended) The apparatus of claim 29, wherein the first arm is operably coupled to an apparatus that positions the first arm with respect to the entry point of the object containing the target area so a long axis of the penetrating-memberneedle passes through the target area.
- 51. (Previously Presented) The apparatus of claim 42, wherein the first arm is operably coupled to an apparatus that positions the first arm with respect to the entry point of the object containing the target area so a long axis of the needle passes through the target area.
- 52. (Currently Amended) The apparatus of claim 1, wherein the first drive mechanism is configured and arranged to translate the first arm so that the penetrating memberneedle proximal portion moves along a translation axis that passes through the target area.
- 53. (Previously Presented) The apparatus of claim 29, wherein the first drive mechanism is configured and arranged to translate the first arm so that the penertrating member proximal portion moves along a translation axis that passes through the target area.

D. Stoianovici, et al. U.S.S.N.: 09/943,751 Page 14 of 18

54. (Previously Presented) The apparatus of claim 42, wherein the first drive mechanism is configured and arranged to translate the first arm so that the needle moves along a translation axis that passes through the target area.

55. (Canceled)

- 56. (New) An apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the penetrating member having a translational axis, said apparatus comprising:
- a first arm being configured and arranged to rotatably support the penetrating member about the translational axis of the penetrating member;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member along its translational axis in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area;
- a second drive mechanism being coupled to the penetrating member and being configured and arranged so as to cause the penetrating member to rotate about the translational axis of the penetrating member; and

wherein the second drive mechanism comprises a gear member secured to the penetrating member and being mechanically coupled to a motor such that operation of the motor causes the penetrating member to rotate about its translational axis,

wherein the second drive mechanism further includes a drive gear that is mechanically coupled to the motor and the penetrating member gear member so that the penetrating member gear member rotates responsive to rotation of the drive gear.

D. Stoisnovici, et al. U.S.S.N.: 09/943,751 Page 15 of 18

- 57. (New) An apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area, the penetrating member having a translational axis, said apparatus comprising:
- a first arm being configured and arranged to rotably support the penetrating member about the translational axis of the penetrating member;
- a first drive mechanism being coupled to the first arm and being configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area;

wherein the first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates;

- a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm; and
- a second drive mechanism being coupled to the penetrating member and being configured and arranged so as to cause the penetrating member to rotate about the translational axis of the penetrating member,

the second drive mechanism comprising a gear member secured to the penetrating member, and a drive gear that is mechanically coupled to the motor and the penetrating member gear member so that the penetrating member gear member rotates responsive to rotation of the motor.